510(K) Summary

DEC 2 1 2012

This 510(k) Summary is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K122948

1. Submitter's Identifications:

Company Name :	GEMORE TECHNOLOGY CO., LTD.
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2. Name of the Device:

Trade/Device Name: Gemore GEM-STIM Combo Stimulator / Model GM304 /GM504/GM384/GM394.

Regulation Number: 21 CFR 882.5890, 21 CFR 882.5850, and Unclassified.

Regulation Name: Power muscle stimulator, Transcutaneous electrical nerve stimulator for pain relief, and Interferential current therapy stimulator.

Regulatory Class: II

Product Code: GZJ, IPF, and LIH

3. Information of the 510(k) Cleared Device (Predicate Device):

Gemore GEM-TWIN TENS/ Model GM38Y/Z (K042559).

4. Device Description:

The GEM-STIM Combo Stimulator; Model: GM304/GM504/GM384/GM394 is the combination of transcutaneous electrical nerve stimulator(TENS) and Interferential stimulation (IF) used for pain relief and/or powered muscle stimulator(EMS) by applying an electrical current to electrodes, which are attached on the patient's skin. The output and waveform is adjustable according to the situation of patient.

The GEM-STIM Combo Stimulator; Model: GM304/GM504/GM384/GM394 consist mainly of two parts: the stimulus generator, electrode. The stimulus generator generates the output current specified as the input of controller. The output port transmits the output current to the electrode, which is attached to the patient's skin so as to transmit this stimulus current to the patient for pain relief or muscle stimulation of intended use purpose.

The GEM-STIM Combo Stimulator; Model: GM304/GM504 is basically the dual output channels unit which includes several different operation modes as mentioned on the comparison table. These operation modes are generated from the software control by using the microprocessor as its main control unit. And the model GM384/GM394 is the 4 channels model with the housing to install two independent units of GM504 and to provide the similar operation buttons which allow each unit of device being operated independently as that of the model GM504.

Basically the new models GM304/GM504/GM384/GM394 was developed from the predicate model GM38Y/Z (K042559). For the new models GM304/GM504/GM384/GM394, the stimulation waveform, significant specification, and the indication for use(IFU) were remained the same as that of Gemore 510(K) cleared predicate model GM38Y/Z (K042559).

5. Intended Use:

<1> For Transcutaneous electrical nerve stimulator.

This device is a prescription device and only for symptomatic relief of chronic intractable pain.

<2> For Power Muscle Stimulator.

- Relaxation of muscle spasms.
- Prevention or retardation of disuse atrophy.
- Increasing local blood circulation.
- Muscle re-education.
- Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis.
- Maintaining or increasing range of motion.

<3> For Interferential Stimulator.

The device is an interferential stimulator with TENS indications used for symptomatic relief and management of chronic intractable pain.

6. Substantial Equivalence Comparison

The GEM-STIM Combo Stimulator; Model: GM304/GM504/GM384/GM394 has output characteristics and controls that are identical to those of the predicate devices. The new device GM304/GM504/GM384/GM394 is considered as Substantial Equivalent to the function of chosen 510K chosen predicate devices:

1> The TENS/EMS function of GM304/GM504/GM384/GM394 is substantial equivalent to GM38Y/Z (K042559) whose Y & Z is "0TE".

2> The Pre-program stimulator function of GM304/GM504/GM384/GM394 is substantial equivalent to GM38Y/Z (K042559) whose Y & Z is "0PE".

3> The IF TENS function of GM304/GM504/GM384/GM394 is substantial equivalent to GM38Y/Z (K042559) whose Y & Z is "2IF".

7. Discussion of Non-Clinical Tests Performed Determination of Substantial Equivalence are as follows:

Compliance to applicable voluntary standards includes ANSI/AAMI, NS4-1985, as well as IEC 60601-1, and IEC 60601-1-2 requirements.

In addition to the compliance of voluntary standards, the software verification has been carried out according to the FDA software guidance.

8. Conclusions

The Gemore GEM-STIM Combo stimulator, model GM304/GM504/GM384/GM394, has the same intended use and technological characteristics as the cleared device of GM38Y/Z (K042559). Moreover, verification and validation tests contained in this submission demonstrate that the difference in the submitted demonstrate that the difference in the submitted models could maintain the same safety and effectiveness as that of cleared device.

In the other words, those engineering difference do not: (1) affect the intended use or (2) alter the fundamental scientific technology of the device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

December 21, 2012

Gemore Technology Company, Ltd.
% Mr. Boden S. P. Lai
General Manager
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Re: K122948
Trade/Device Name: GEM-STIM Combo Stimulator/Model GM304/GM504/GM384/GM394
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous electrical nerve stimulator for pain relief
Regulatory Class: Class II
Product Code: GZJ, IPF, LIH
Dated: September 21, 2012
Received: September 24, 2012

Dear Mr. Lai:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Victor Krauthamer -S

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear, Nose
and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): k122749

Device Name: GEM-STIM Combo Stimulator; Model: GM304/GM504/GM384/GM394.

Indications For Use:

<1> For Transcutaneous electrical nerve stimulator.
This device is a prescription device and only for symptomatic relief of chronic intractable pain.

<2> For Power Muscle Stimulator.
- Relaxation of muscle spasms.
- Prevention or retardation of disuse atrophy.
- Increasing local blood circulation.
- Muscle re-education.
- Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis.
- Maintaining or increasing range of motion.

<3> For Interferential Stimulator.
The device is an interferential stimulator with TENS indications used for symptomatic relief and management of chronic intractable pain.

PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use V OR Over-The-Counter Use ___

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Neurological and Physical Medicine Devices
510(k) Number k122749